Nos. 22-2153, 23-1952

In the United States Court of Appeals
For the Federal Circuit

SALIX PHARMACEUTICALS, LTD.,
SALIX PHARMACEUTICALS, INC.,
BAUSCH HEALTH IRELAND LTD., ALFASIGMA S.P.A.,
Plaintiffs - Appellants

v.

NORWICH PHARMACEUTICALS INC.,
Defendant - Cross-Appellant

On Appeal from the United States District Court for the
District of Delaware (Hon. Richard G. Andrews, presiding)
Case No. 1:20-cv-00430

RESPONSE AND REPLY BRIEF OF APPELLANTS

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CERTIFICATE OF INTEREST

Case Numbers	22-2153, 23-1952
Short Case Caption	*Salix Pharmaceuticals, Ltd. v. Norwich Pharmaceuticals Inc.*
Filing Party/Entity	Appellants / Salix Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc., Alfasigma S.p.A., Bausch Health Ireland Ltd.

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

/s/ William R. Peterson
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Alfasigma S.p.A.

Dated: October 12, 2023

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Salix Pharmaceuticals, Ltd.	Not Applicable	Bausch Health Companies Inc.

Salix Pharmaceuticals, Inc.	Not Applicable	Bausch Health Companies Inc.
Bausch Health Ireland Ltd.	Not Applicable	Bausch Health Companies Inc.
Alfasigma S.p.A.	Not Applicable	Turytes S.p.A.

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☑ Yes ☐ No ☐ N/A (amicus/movant)
(*See* Notice of Related Case Information at Dkt. 9 in No. 23-1952.)

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable

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INTRODUCTION

Salix is entitled to relief. Norwich does not argue that it proved that the RFIB2001 Press Release was "by others" under pre-AIA Section 102(a). Norwich assumes that Salix bore the burden on this issue, but it cites no authority for that proposition. It has no answer to this Court's cases placing the burden on the challenger to "establish [a] reference was prior art 'by another.'" *Google LLC v. IPA Techs. Inc.*, 34 F.4th 1081, 1086 (Fed. Cir. 2022). The district court's reliance on the RFIB2001 Press Release as prior art was harmful error and, at a minimum, requires remand.

Independently, Norwich fails to defend the finding that a skilled artisan would have had a reasonable expectation of success in treating IBS-D with the specific dosage claimed (1,650 mg/day) in the IBS-D Claims. Norwich does not deny the key fact: "The highest dosage for which the district court found prior art reported success in treating IBS-D was 1,200 mg/day." Salix Br. 3.

Norwich argues that any disclosure of a range—without any disclosure of its effectiveness—somehow creates an expectation of success. Neither logic nor precedent supports this theory. This Court's cases recognize that if a range is known to succeed, then skilled artisans would expect success from any value within that range. But this reasoning makes sense only if the range actually **is** expected to be successful.

Norwich also retreats from the district court's analysis, relying on materials that the district court did not find to be prior art and prior art that the district court did not find relevant to expectation of success (because the references did not report success in treating IBS-D). But Norwich cannot defend the district court's judgment on these grounds.

Under the facts found by the district court, the highest dosage for which the prior art disclosed positive results in treating IBS-D was 1,200 mg/day. Appx39. Applying this Court's precedent to these findings, there is no expectation of success in the claimed 1,650 mg/day dosage, which falls nearly 40% outside the range known or reasonably expected to treat IBS-D.

Norwich also fails to defend the district court's application of the incorrect obviousness standard to the Polymorph Claims.

If this Court grants Salix's requested relief on its IBS-D Claims, then Norwich's cross-appeal will become moot because the Amended ANDA cannot be approved. For these reasons, we begin with the argument in reply and follow with the portions of the brief concerning the cross-appeal.

ARGUMENT IN REPLY

I. Norwich Fails to Defend the Invalidation of the IBS-D Claims.

The district court committed two independent errors in holding the IBS-D Claims invalid as obvious.

First, the district court erred by treating the RFIB2001 Press Release as prior art. This was the central piece of evidence the district court relied upon in finding an expectation of success, and the error was harmful.

Second, even considering the RFIB2001 Press Release, the district court erred by finding an expectation of success in using the claimed dosage (1,650 mg/day) to achieve the claimed successful treatment of IBS-D.

A. Norwich Does Not Succeed in Defending the District Court's Reliance on the RFIB2001 Press Release as Prior Art.

1. Norwich bore the burden to prove that the RFIB2001 Press Release reported work "by others."

Salix's opening brief raised a straightforward argument: (1) Norwich bore the burden to prove by clear and convincing evidence that the RFIB2001 Press Release was "by others" to qualify it as prior art under pre-AIA Section 102(a); and (2) Norwich failed to satisfy that burden.

Norwich's brief commits the same error as the district court, which placed the burden on Salix to present evidence "that the press release was derived from the inventor's work." Appx41.

The placement of the burden of proof is a legal issue this Court reviews de novo. Salix Br. 29. Salix addressed this issue at length in its opening brief (at 32-33), but Norwich responds with only three unpersuasive sentences. Norwich Br. 40-41.

a. The burden of proof did not "shift"—it always remained with Norwich.

The burden to prove that the RFIB2001 Press Release was prior art—including proving that it was "by others"—always remained with Norwich and never shifted. *E.g.*, *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996) ("[The challenger] bore the burden of persuasion by clear and convincing evidence on all issues relating to the status of [a reference] as prior art[.]"); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008) (explaining that the burden of persuasion "[n]ever shifts to the other party"); *Google*, 34 F.4th at 1085-86 (applying these principles to whether art was "by others").

The burden of persuasion never shifted, and Norwich failed to satisfy it.

b. A burden of production shifts, if at all, only when the burden of persuasion is satisfied.

Norwich asserts that Salix bore "the 'burden of going forward with rebuttal evidence,'" i.e., the burden of production. Norwich Br. 40-41 (quoting *Mahurkar*, 79 F.3d at 1576-77).

Norwich is wrong. The burden of production shifts—if at all—only after the party with the burden of persuasion presents evidence that satisfies its burden: "Though the burden of proving the fact remains where it started, once the party with this burden establishes a prima facie case, the burden to 'produce evidence' shifts." *Dir., Off. of Workers' Comp. Programs v. Greenwich Collieries*, 512 U.S. 267, 273 (1994); *see also Mahurkar*, 79 F.3d at 1577 (citing *Greenwich Collieries* regarding the burdens of persuasion and production); *Moore v. Kulicke & Soffa Indus., Inc.*, 318 F.3d 561, 566 (3d Cir. 2003) (discussing burdens of proof and persuasion).

Here, the burden of production could have shifted to Salix only if Norwich first presented sufficient evidence that, if credited, would show that the RFIB2001 Press Release was "by others" under pre-AIA Section 102(a).[1]

c. Norwich did not present evidence satisfying its burden to show that the press release was "by others."

Norwich failed to present evidence that the RFIB2001 Press Release reported the work of others, and its brief identifies no evidence supporting this finding.

[1] For example, regarding whether a reference predates the date of invention, a challenger makes out a prima facie case by showing that the reference predates the filing date of the patent. *Mahurkar*, 79 F.3d at 1577. This evidence satisfies the challenger's burdens of production and persuasion that the reference was "before the invention thereof by the applicant." 35 U.S.C. § 102(a) (pre-AIA). If the patentee nonetheless contends that the invention date predated the filing date, the patentee must "come forward with evidence of an earlier date of invention." *Mahurkar*, 79 F.3d at 1577.

The closest Norwich comes is suggesting that "Salix," a corporate entity, conducted the study. Norwich Br. 40. But an inventive entity is a combination of natural persons—a corporation cannot be an inventor. *Thaler v. Vidal*, 43 F.4th 1207, 1209 (Fed. Cir. 2022); *see also Google*, 34 F.4th at 1084 (discussing inventive entities). Attributing the press release to "Salix" is not evidence that the RFIB2001 Press Release reported the work of "others" because the named inventors were Salix employees.

The face of a reference frequently satisfies a challenger's burden to show that the reference is the work of others. *E.g.*, *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 969 (Fed. Cir. 2014) (involving a reference describing itself as written for "a long list of study group members" in which the named inventor "does not appear").

But the face of the RFIB2001 Press Release does not indicate that it is the work of others. Norwich's own expert confirms that the press release quoted Bill Forbes, a named inventor. Appx3178.

* * *

Norwich bore the burden of persuasion to show by clear and convincing evidence that the RFIB2001 Press Release was prior art under pre-AIA Section 102(a), including that it was "by others." "Failure to prove the matter as required by the applicable standard"—as Norwich failed to do here—"means that the party with

the burden of persuasion loses on that point." *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378–79 (Fed. Cir. 2015) (quoting *Tech Licensing*, 545 F.3d at 1327).

2. Norwich's argument regarding the Joint Pretrial Order is meritless.

Norwich recognizes that Salix listed the RFIB2001 Press Release as disputed prior art in the Joint Pretrial Order. Norwich Br. 39 ("list[ed] this reference").

Norwich is wrong to suggest (at 38-39) that Salix was required to identify "derivation" expressly in the Joint Pretrial Order. Third Circuit law requires "pretrial orders [to be] liberally construed to permit the parties to advance their cases." *Shell Petroleum, Inc. v. United States*, 182 F.3d 212, 218 (3d Cir. 1999). General statements are "liberally construed to embrace all legal and factual theories inherent in the issues defined therein." *U.S. Gypsum Co. v. Schiavo Brothers, Inc.*, 668 F.2d 172, 181 (3d Cir. 1981).

Whether Norwich proved that the RFIB2001 Press Release was "by others" is inherent in the issue "[w]hether Norwich has proven by clear and convincing evidence that [the RFIB2001 Press Release] qualif[ies] as prior art to the Asserted IBS-D Patent claims." Appx1457. Salix made clear that it intended to hold Norwich to its burden of proving the status of the press release as prior art.

Norwich cites an unpublished decision from the District of New Jersey. But in that case, a portion of the pretrial order specifically discussed "unexpected

results," and the plaintiff failed to include a particular theory (unexpected results related to gender) within that section. *Prometheus Lab'ys Inc. v. Roxane Lab'ys, Inc.*, No. 11-1241, 2014 WL 12607728, at *19 (D.N.J. May 21, 2014). There is nothing similar in the Joint Pretrial Order at issue.

Norwich appears to premise its argument about the Joint Pretrial Order on the assumption that "Salix bore the burden of production on the derivation theory." Norwich Br. 39. Norwich cites no authority for this erroneous assertion.

The issue Salix listed in the Joint Pretrial Order—whether Norwich proved that the RFIB2001 Press Release was prior art—encompasses whether Norwich satisfied its burden to prove that the press release was "by others."

3. Norwich's harmless error argument is meritless.

Because the district court erred in relying on the RFIB2001 Press Release as prior art, this Court must vacate and remand unless the error was harmless. Norwich erroneously conflates harmful error with "clear error." Norwich Br. 41; *see also id.* 41-44.

An error is harmful if "it affected the decision below." *In re Chapman*, 595 F.3d 1330, 1338 (Fed. Cir. 2010). If this Court "cannot say with confidence that the [district court] would have reached the same conclusion in the absence of" the RFIB2001 Press Release, then the error was harmful. *Id.* at 1339-40.

Norwich does not deny that the RFIB2001 Press Release was the most important evidence the district court relied on in finding an expectation of success, particularly in discounting Salix's evidence of skepticism. Salix Br. 37-39. Given the heavy reliance on the RFIB2001 Press Release throughout the district court's opinion, this Court cannot be confident that the district court would have reached the same result in its absence.

Norwich's response is unpersuasive. The district court rejected Salix's argument that "the RFIB 2001 Protocol did not disclose results," Norwich Br. 45 (quoting Appx41), **because of** the press release. *See* Appx41 ("Salix's press release disclosing success in the RFIB 2001 Protocol study is prior art, and thus a POSA would have known about the RFIB 2001 top-line results as of the priority date."). Similarly, the district court relied primarily on the RFIB2001 Press Release to discount the skeptical prior art literature. *See* Appx42 ("The RFIB 2001 Press Release—which was not cited by Quigley, Vanner, or Drossman—states . . . ."). These facts strongly suggest that the district court would not have reached the same result in the absence of the RFIB2001 Press Release.

The RFIB2001 Press Release was the critical piece of evidence relied on by the district court. Salix Br. 37. Treating it as prior art was harmful error. At a minimum, this Court must vacate and remand.

B. Norwich Fails to Defend the District Court's Finding of an Expectation of Success in Using the Claimed Dosage—1,650 mg/day—to Treat IBS-D.

Remand is unnecessary, however, because the district court erred in finding an expectation of success.

The patents claim a specific dosage (1,650 mg/day), and the "reasonable-expectation-of-success analysis" must be "frame[d] . . . around that specific dosage." *Teva Pharm. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1381 (Fed. Cir. 2021). Norwich needed to prove—by clear and convincing evidence—that skilled artisans would have had a reasonable expectation of success in achieving successful treatment of IBS-D with the claimed dosage.[2]

The district court did not make this finding expressly, and it erred in applying this Court's prior-art-range cases. Norwich fails to defend this analysis.

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[2] It is not enough that "one would reasonably expect the prior art references to operate as those references intended once combined"—"one must have . . . a reasonable expectation of achieving what is claimed." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). Claim 3 of the '667 Patent requires that the administration of rifaximin "trea[t] one or more symptoms of IBS-D in [a] subject 65 years of age or older." Claim 2 of the '569 Patent requires a "durability of response" that "comprises about 12 weeks of adequate relief from [IBS-D symptoms]" after the subject is removed from rifaximin treatment.

The district court did not distinguish between these two limitations. For convenience, we refer to them both as "successful treatment of IBS-D" or "successfully treating IBS-D."

1. Norwich's argument about ranges would eviscerate the reasonable expectation of success.

As detailed in Salix's opening brief, the district court's erroneous analysis of obviousness rested on two findings:

- The prior art "describes positive results from a range of doses," i.e., 1,100 mg/day and 1,200 mg/day.
- The RFIB2001 Protocol involved testing dosages between 1,100 mg/day and 2,200 mg/day.

Appx39. Based on these findings—and nothing else—the district court found the claimed dosage obvious because it fell within the "known range." Appx33-34; Appx39.

Norwich repeats this error. It contends the mere disclosure of a range—standing alone, without any results or reason to believe that using a value within the range would achieve what is claimed—creates an inference that any value within the range is obvious. Norwich Br. 48-49.

a. Neither logic nor law supports Norwich.

Norwich's position is illogical and contrary to this Court's precedent. Its reasoning is a non sequitur: Unless skilled artisans expected that the dosage range in the RFIB2001 Protocol would successfully treat IBS-D, a dosage falling within that range is not evidence that skilled artisans would expect the dosage to successfully treat IBS-D.

Norwich identifies no evidence—and no finding—that the RFIB2001 Protocol taught or suggested to skilled artisans that the entire dosage range being tested would successfully treat IBS-D. The RFIB2001 Protocol is, of course, only a "protocol that doesn't have any results in it." Appx3219.

Moreover, the RFIB2001 Press Release indicated that only the 1,100 mg/day dosage succeeded; the 2,200 mg/day dosage did not. Salix Br. 43 (citing Appx7480; Appx3042). The district court's reference to "the successful RFIB 2001 Protocol results," Appx38, disregards the claimed dosage and fails to acknowledge that the results showed success **only** for 1,100 mg/day ("550 mg twice-a-day," Appx7480).

Norwich cites no case in which this Court accepted the inference it seeks to draw. Every time this Court has relied on a range to find a dosage obvious, the dosage has been within a range known to succeed (or equivalent to a dosage known to succeed). *E.g.*, *Yeda Rsch. v. Mylan Pharms., Inc.*, 906 F.3d 1031, 1043-45 (Fed. Cir. 2018) (relying on regimens "with clinical support"); *see also* Salix Br. 45-47.

This Court has carefully guarded the distinction between experimenting with a therapy and expecting the experiment to be therapeutically effective: "While it may have been obvious to experiment . . . , there is nothing to indicate that a skilled artisan would have had a reasonable expectation that such an experiment would succeed in being therapeutically effective." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 676 F.3d 1063, 1070 (Fed. Cir. 2012). Here,

as in *Teva*, even if prior art "directed a skilled artisan to try" a new dosage, "without showing a reasonable expectation of success, [the challenger] did not prove obviousness." 18 F.4th at 1383.

Norwich's theory would eliminate that distinction. Drawing the inference that Norwich seeks—treating disclosure of a range that skilled artisans would not expect to succeed as somehow creating an expectation of success for any value within that range—would render expectation of success meaningless.

b. As Amici highlight, Norwich's untested-ranges-are-obvious theory would raise particular risks in the pharmaceutical context.

Norwich's proposed rule poses a particular danger in the pharmaceutical context, where current regulations require innovators to register most clinical drug studies and make them publicly available within thirty days of submission. Vanda Amicus Br. at 5-7. These protocols "represent only hypotheses to be tested," not evidence of a reasonable expectation of success. Regeneron Amicus Br. 5; *see also* Vanda Amicus Br. 13.

This case exemplifies the "growing practice among patent challengers of using protocol summary disclosures . . . as prior art in obviousness claims." Regeneron Amicus Br. at 3, 11-14. Norwich errs when it contends that "the court did not solely rely on the RFIB2001 Protocol in finding a reasonable expectation of success." Norwich Br. 54. The district court found other evidence that showed

skilled artisans would have reasonably expected **some dosage** of rifaximin to treat IBS-D successfully.[3] But on the crucial issue—whether skilled artisans would have reasonably expected **the claimed 1,650 mg/day** to successfully treat IBS-D—the RFIB2001 Press Release was the **only** evidence relied on by the district court. The opinion mentions only a single dosage exceeding 1,200 mg/day: the 2,200 mg/day dosage that was tested (unsuccessfully) in the RFIB2001 Protocol.

This reasoning, if accepted, would pose a significant threat to pharmaceutical patents. Companies such as Salix spend billions of dollars in clinical trials, Regeneron Amicus Br. 14, which they recoup through patent rights secured when those trials discover new methods of treatment. But if mere disclosure of a test protocol renders obvious everything being tested, then the requirement to disclose clinical trials itself defeats patent eligibility.

Norwich's argument is absurd in any context but is particularly dangerous in the pharmaceutical context.

[3] As discussed in Salix's opening brief (at 11-12), the medical community rejected Dr. Pimentel's work, including Pimentel 2006. But the district court concluded that the RFIB2001 Press Release overcame this skepticism. Salix Br. 18-19.

2. In evaluating expectation of success, the district court relied only on prior art reporting "positive results."

Norwich accuses Salix of demanding "efficacy data" and "positive results." Norwich Br. 48-49. But Norwich's real dispute is with the district court, which relied on the "positive results" disclosed in the prior art:

> As of the priority date, the prior art disclosed positive results in using rifaximin to treat IBS-D for a range of doses. The asserted IBS-D claims describe a dosing regimen within the known range.

Appx34.

Norwich could have tried to prove expectation of success in other ways. For example, Norwich might have shown that rifaximin's effectiveness in treating IBS-D depended only on the total monthly intake and that 49,500 mg/month was known to treat IBS-D successfully. *See Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331-32 (Fed. Cir. 2014). Or Norwich might have proven that skilled artisans would have expected rifaximin to treat IBS-D successfully at dosages identical to a different drug. *See Anacor Pharm., Inc. v. FlatWing Pharm., LLC*, 825 F. App'x 811, 815-16 (Fed. Cir. 2020). Or if Salix had claimed 1,210 mg/day, Norwich might have demonstrated that the claimed dosage was "close enough" to the known 1,200 mg/day "such that one skilled in the art would have expected them to have the same properties." *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003).

But Norwich introduced no such evidence, and the district court did not make these findings. To the extent the district court found an expectation of success in the

claimed dosage, it relied on reports of "positive results" for various dosages in using rifaximin to treat IBS-D. Appx39. The claimed dosage, however, is far outside the range for which positive results had been reported.

3. Norwich cannot defend the judgment based on findings not made and evidence not credited by the district court.

Perhaps recognizing the weakness in the district court's reasoning, Norwich's brief departs from the district court's analysis, relying on findings the court did not make and evidence it did not credit.

a. The district court did not find that Weinstock and Jolley are prior art, and they could not have created a reasonable expectation of success.

Norwich discusses the Weinstock and Jolley references as alleged evidence of pre-2008 uses of rifaximin in dosages exceeding 1,650 mg/day. Norwich Br. 42, 51-52. But the district court's opinion never mentions Weinstock or Jolley, let alone as support for finding an expectation of success.

Neither reference is prior art. Weinstock is a letter discussing a retrospective chart review published in 2011, long after the priority date for the IBS-D Patents. Appx7587-7589; *see also* Salix Br. 8-9 (explaining the flaws in retrospective chart reviews). To the extent Norwich relies on treatment records underlying Weinstock, Norwich's expert admitted they were not publicly available before February 2008. Appx3228-3229. Jolley is another retrospective chart review published in 2011. Appx368; Appx3166. Dr. Jolley's underlying treatment records were not publicly

available before February 2008. Appx3231. And Norwich failed to offer any evidence that physicians, patients, or pharmacists publicly disclosed Drs. Weinstock's and Jolley's off-label uses of rifaximin. Appx3227-3228; Appx3231.

The cases cited by Norwich do not support its arguments. One involved anticipation, which Norwich does not argue. *UCB, Inc. v. Watson Lab'ys Inc.*, 927 F.3d 1272, 1291 (Fed. Cir. 2019). The other involved publication of a system, not confidential treatment of a single patient. *See Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1305 (Fed. Cir. 2006) (concluding that a doctor's practice was "sufficiently publicly accessible to qualify as prior art" because he "promoted his system" and "distributed his instruction sheet").

Moreover, Norwich introduced no evidence that skilled artisans were aware of Drs. Weinstock's and Jolley's patient treatments; thus, their practices could not have given others the reasonable expectation of success. *E.g.*, *Life Techs., Inc. v. Clontech Lab'ys, Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000) ("Reasonable expectation of success is assessed from the perspective of the person of ordinary skill in the art.").

Norwich fails to show clear error in the district court not considering Weinstock and Jolley as prior art or evidence of a reasonable expectation of success.

b. Norwich's remaining prior art does not report successful treatment of IBS-D symptoms or otherwise create an expectation of success.

Norwich also mentions several other references: Lin (Appx4721), Scarpellini (Appx4663), Lauritano (Appx7267), and Viscomi (Appx4669). Although the district court found that these references were prior art, it did not rely on them in its analysis or find they created a reasonable expectation of success in using the claimed dosage to treat IBS-D. None reports successful use of rifaximin in treating IBS-D.

Lin discusses using 1,200 mg/day for "successful partial eradication of SIBO," not relief of IBS-D symptoms. Appx4742. Viscomi, a patent application, suggests an "exemplary dosage range . . . from 100 to 1800 mg per day" of rifaximin as possible treatment for numerous diseases, including "irritable bowel syndrome, diarrhea, microbe associated diarrhea, *Clostridium difficile* associated diarrhea, travelers' diarrhea, small intestinal bacterial overgrowth, Crohn's disease, chronic pancreatitis, pancreatic insufficiency, colitis, hepatic encephalopathy, or pouchitis." Appx4690 ¶ 198. Viscomi neither mentions IBS-D nor identifies a rifaximin dosage for treatment of IBS-D and directs that "actual dosage levels" should be "varied so as to obtain an amount of the active ingredient which is effective to achieve the desired therapeutic response." Appx5694 ¶ 246. Scarpellini and Lauritano discuss using rifaximin "for the treatment of small intestinal bacterial overgrowth treatment," not IBS or IBS-D. Appx4663; Appx7267.

Norwich fails to show—or even argue—clear error in the district court's decision not to treat these references as evidence of an expectation of success, and this Court cannot affirm based on a finding of fact that the district court did not make. *E.g.*, *Tris Pharma, Inc. v. Actavis Lab'ys FL, Inc.*, 755 F. App'x 983, 988 (Fed. Cir. 2019).

Applying the correct legal standard to the facts found by the district court, Norwich failed to establish an expectation of success in treating IBS-D using the claimed dosage. Norwich's reliance on findings the district court did not make (despite Norwich's invitation) and evidence it did not credit is improper.

4. Salix's arguments apply equally to all three combinations asserted by Norwich.

Salix's arguments above apply equally to all three prior art combinations. Norwich offers no reasoned argument that the district court could have reached a different conclusion regarding expectation of success for a different combination. Because "the record permits only one resolution of the factual issue," *Pullman-Standard v. Swint*, 456 U.S. 273, 292 (1982), this Court need not remand. Norwich failed to show a reasonable expectation of success in successfully treating IBS-D with the claimed dosage for any asserted combination.

This Court should reverse the determination that the IBS-D Claims are obvious, hold the claims valid, and order the effective date of any approval of

Norwich's ANDA be not earlier than expiration of the IBS-D Patents. In the alternative, if necessary, this Court should remand to the district court.

II. The District Court Erred in Holding the Polymorph Claims Invalid as Obvious.

For the Polymorph Claims, the issue is the test for obviousness. The district court held, without the benefit of this Court's affirmance in *Pharmacyclics*, that claims directed to a particular form of rifaximin were rendered obvious by showing that a skilled artisan would have had a motivation to "consider [rifaximin] as a potential drug candidate," Norwich Br. 56, and a reasonable expectation of "characterizing" it. Norwich Br. 57.

But *Pharmacyclics LLC v. Alvogen, Inc.*, No. 2021-2270, 2022 WL 16943006 (Fed. Cir. Nov. 15, 2022), *Grunenthal GMBH v. Alkem Lab'ys Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019), and general obviousness principles do not set the bar so low. Norwich was required to prove by clear and convincing evidence that a skilled artisan would have had a motivation and reasonable expectation of success in developing **the specific claimed polymorph**, not in discovering **a** rifaximin polymorph. Norwich presents no argument on appeal under this proper test.

A. Norwich Mischaracterizes the Obviousness Test.

Norwich's defense focuses on irrelevant points: according to Norwich, a skilled artisan may "have been motivated to characterize rifaximin produced by

Cannata," and form β may have been identified from characterizing rifaximin. Norwich Br. 57.

But as Salix explained in its opening brief (at 52-55), those facts are insufficient to show obviousness. There is no evidence that skilled artisans would have been motivated or expected to develop a form of rifaximin with the specific claimed x-ray diffraction peaks of β. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (describing obviousness as whether a skilled artisan "would have been led to make the combination recited in the claims"); *Intelligent Bio-Sys.*, 821 F.3d at 1367 ("[O]ne must have a motivation to combine accompanied by a reasonable expectation of achieving what is claimed in the patent-at-issue.").

Norwich argues there is no special test for polymorph claims. Norwich Br. 58. Salix has never argued that polymorphs should be treated differently from other claims. To the contrary, as Salix explained in its opening brief (at 49-51), this Court's application of traditional obviousness principles—rooted in *Graham* and *KSR*—to similar polymorph claims defeats Norwich's arguments. Although the test for obviousness is flexible, the law requires both a motivation to combine and an expectation of success in finding the claimed invention (i.e., rifaximin β).

Norwich next argues that the motivation to combine is "not limited to the same motivation that may have motivated the inventors." Norwich Br. 59. This is no answer to the requirement that a skilled artisan be motivated to "achiev[e] what is

claimed in the patent-at-issue," *Intelligent Bio-Sys.*, 821 F.3d at 1367, a requirement Norwich does not address.

Norwich argues that if Salix were correct, "no uncharacterized or unknown crystal form (or compound, for that matter) could ever be obvious." Norwich Br. 59. Not so. There may be circumstances in which enough is known about an unknown crystallized form that skilled artisans would have been motivated to create it and had expectation of success in doing so. But here, where (1) "rifaximin's polymorphism was unknown as of the priority date," Appx13, (2) skilled artisans "would not have been able to predict in advance the existence of any crystalline forms" nor "their properties," Appx3459, and (3) Norwich cites to no evidence of motivation to arrive at the claimed invention, the district court erred in holding the Polymorph Claims obvious.

Norwich's focus on the alleged natural relationship between the various other polymorphs of rifaximin and form β, Norwich Br. 64-68, is both inaccurate (as discussed below) and irrelevant to obviousness. None of the polymorphs Norwich identifies was known at the time of the invention, and even the fact that rifaximin **could be** polymorphic was unknown. Appx13.

B. Norwich Fails to Distinguish *Pharmacyclics* and *Grunenthal*.

Norwich attempts to distinguish *Pharmacyclics* and *Grunenthal* on the ground that the prior art in this case, unlike those cases, lacked teachings that any crystalline

forms existed. Norwich Br. 59-61. But neither decision turned on those particular facts. To the contrary, the *Pharmacyclics* district court explicitly found that a skilled artisan "would have been motivated to develop *a* crystalline form of ibrutinib." 556 F. Supp. 3d 377, 412 (D. Del. 2021).

According to Norwich, the fact that less was known about rifaximin (that it had not been "publicly characterized") than about the polymorph in *Grunenthal* means that a skilled artisan would have been more motivated to investigate rifaximin than the polymorph in *Grunenthal*. Norwich's attempt to distinguish *Grunenthal* on the ground that less—not more—was known turns the obviousness standard on its head.

Finally, Norwich relies on broad and general statements, such as that "the expectation of success need only be reasonable, not absolute" and "obviousness may be found even where there is some degree of unpredictability in the art." Norwich Br. 63. These statements do not justify affirmance here in view of this Court's detailed opinions in *Pharmacyclics* and *Grunenthal*. Salix also does not "blindly deman[d] the same motivation to combine the prior art in all polymorph cases," Norwich Br. 61, but there must be **a** motivation, and Salix relies on the most applicable cases—i.e., the only two cases where this Court has addressed polymorphism in the context of obviousness—and explains why no principled basis exists to reach a different result in this case.

C. Norwich's Alternative Anticipation Argument Should Be Rejected.

To prove that a claim is anticipated, Norwich was required to "present clear and convincing evidence that a single prior art reference discloses, either expressly or inherently, each limitation of the claim." *In re Cruciferous Sprout Litig*., 301 F.3d 1343, 1349 (Fed. Cir. 2002). This Court reviews "the district court's findings of fact on inherent anticipation for clear error." *Allergan*, 754 F.3d at 961. Norwich has not shown that the district court clearly erred in finding that Norwich failed to present clear and convincing evidence that Cannata, Appx4526-4532, inherently discloses all elements of claim 4 of the '199 patent.

The proper inquiry is whether the claimed β polymorphs necessarily result from practicing Cannata. *See, e.g., Allergan*, 754 F.3d at 960-61 (affirming judgment that claims were not inherently anticipated where the prior art only showed that the limitation might occur, not that it inevitably occurred). That a skilled artisan may "have been able" to create the β polymorph based on Cannata's disclosure is not enough to prove inherent anticipation. *Galderma Lab'ys, L.P. v. Teva Pharm. USA, Inc*., 799 F. App'x 838, 845 (Fed. Cir. 2020).

There is no dispute that wet rifaximin can result in polymorphs other than β: namely, α, δ, ε, **and γ**. *See* Norwich Br. 65 (citing Appx4705). As to the α, δ, and ε polymorphs, Norwich argues that as a law of nature rifaximin β is a necessary precursor. But the district court found—and Norwich does not dispute—that

Norwich's expert's "opinion does not clearly support the conclusion that, as a law of nature, rifaximin β is a necessary precursor to rifaximin α, δ, and ε." Appx9. The district court simply found that Norwich's expert's testimony did not prove this key point. Indeed, as the district court recognized, Norwich's expert neither performed experiments nor tried to recreate rifaximin using Cannata's disclosed procedures to prove the law-of-nature theory. Appx9. Norwich fails to show clear error in this finding.

Norwich relies instead on attorney argument, but this Court has long recognized that "expert testimony regarding matters beyond the comprehension of laypersons is sometimes essential, particularly in cases involving complex technology." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1240 n.5 (Fed. Cir. 2010); *see also Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1267 (Fed. Cir. 2008) (affirming the requirement of expert testimony where "th[e] subject matter [wa]s sufficiently complex to fall beyond the grasp of an ordinary layperson"). This complex issue is one on which Norwich needed—but failed to present—sufficient expert testimony. Appx9.

Rifaximin γ is also a problem for Norwich. If rifaximin γ forms, then β may not. The diagram on Appx4705 shows how rifaximin γ can form from "fast crystallization, or omission of water washings." Norwich implies (at 71) that Salix's expert Dr. Meyerson conceded Cannata could not be practiced with fast

crystallization or omission of water washings, but the testimony from Dr. Meyerson that Norwich relies on says nothing about rifaximin γ, fast crystallization, or omission of water washings. Appx3474. It instead remarks how two of Cannata's examples could not involve "evaporation slow or fast." Appx3474. Contrary to Norwich's assertion, there is no clear and convincing evidence that rifaximin β necessarily would have formed as an intermediate.

Norwich also improperly relies on references that post-date the priority date of the '199 patent to fill Cannata's gaps. *See Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 726 F.2d 724, 726-27 (Fed. Cir. 1984) (improper to make obviousness-type arguments based on additional materials when addressing inherent anticipation).

Viscomi 2008 and Braga 2012 do not follow Cannata's procedures. They disclose processes for preparing rifaximin that closely follow those in the '199 Patent, processes which significantly differ from those in Cannata. Appx3471. As the district court recognized, "[e]xperiments that do not follow the prior art procedure alleged to inherently anticipate cannot show inherent anticipation." Appx11.

Finally, contrary to Norwich's assertion (at 71), there was record evidence that process differences in each step of a chemical synthesis—including the reaction, washing/filtering, drying, and crystallization steps—can impact the impurity profile

and influence the outcome of the crystallization. Appx3462-3465, Appx3470, Appx3494. In any event, Norwich's improper attempt to shift the burden to Salix to show non-inherency should be rejected. Norwich Br. 71. Norwich failed to prove inherency by clear and convincing evidence, and it has failed to show the district court clearly erred.

STATEMENT OF ISSUES ON CROSS-APPEAL

1. Whether the district court erred by entering a Section 271(e)(4) order that sets the effective date for approval of ANDA No. 214369, without permitting Norwich to receive immediate final approval by amending the ANDA after entry of judgment.

2. Whether the district court abused its discretion in denying Norwich's motion to modify the judgment under Rule 60(b).

STATEMENT OF THE CASE RELATING TO CROSS-APPEAL

After Norwich filed ANDA No. 214369, Salix filed suit under the Hatch-Waxman Act. Appx61. Among other grounds of infringement, Salix asserted that the indications on the ANDA's label would induce infringement of method-of-treatment claims in several of Salix's patents. Appx61. The parties litigated for the next twenty-eight months, through trial and a decision by the district court. Appx77. During the years that the case was pending, Norwich never suggested amending its ANDA to modify its proposed label.

As the case proceeded, the parties made strategic litigation decisions. Salix, for example, agreed to forgo certain discovery. Appx1321. Salix's Rule 30(b)(6) deposition notice included actual, potential, or contemplated uses for Norwich's ANDA Product. But based on Norwich's label and its agreement not to offer testimony at trial on these subjects, Salix agreed not to compel testimony. Appx1321.

Similarly, consistent with the district court's direction, Appx167-168, Salix limited the number of claims it asserted. Although Salix contended that Norwich's ANDA infringed dozens of Salix's patents, Salix asserted only nine claims at trial. When presenting evidence and argument, Salix divided time between the HE Patents, IBS-D Patents, and Polymorph Patents. Nearly half the trial was spent

litigating infringement and validity of the HE Claims, with five experts testifying on these issues.

After trial, the parties jointly asked the Court to enter a final judgment of non-infringement regarding the claims not asserted at trial. Appx3709. The stipulation provided that "Norwich's current ANDA No. 214369" did not infringe the claims of Salix's patents, but it defined these phrases narrowly to include only "amendments or supplements to the ANDA that **do not change the indications of use**." Appx3710 n.1 (emphasis added).

After Trial, Norwich Mentions a Hypothetical Future Amendment

Four months after trial, on July 28, 2022, the district court directed the parties to file a proposed final judgment reflecting the conclusion that Norwich's ANDA would induce infringement of all asserted claims but that the IBS-D Claims and Polymorph Claims were invalid. Appx77.

In a response filed on August 3, Norwich suggested for the first time that it might seek to amend its ANDA to carve out the HE indication. Norwich had not actually amended its ANDA at that time; it admitted that it asked to limit the judgment based on what it **might** do in the future. *See* Appx3896 ("If Norwich were to carve out the HE indication from its proposed ANDA labeling . . . .").

Salix countered that Norwich improperly sought a determination whether "Norwich's ANDA would induce infringement in the future based on hypothetical

changes Norwich may make to its ANDA." Appx3893. "The parties never litigated the issue of what a future, hypothetical 'skinny' label would look like, and whether it would infringe the Asserted HE Patents." Appx3894.

The district court agreed with Salix and followed the plain language of the Hatch-Waxman Act:

> The scope of my ruling is that the HE patents are not invalid, and that the HE indication would infringe the HE patents. Norwich's proposed ANDA has the HE indication. I cannot rule on facts that are not before me. That Norwich may seek to carve out the HE indication as permitted by 21 U.S.C. § 355(j)(2)(A)(viii) is immaterial to this analysis.

Appx48. Accordingly, the judgment ordered that "the effective date of any final approval by the Food and Drug Administration ('FDA') of Norwich's ANDA No. 214369" would be after expiration of the HE Patents. Appx51.

Norwich Moves to Amend the Judgment

After Salix filed a notice of appeal, Appx3965, Norwich moved to modify the judgment under Rule 60(b) in light of a labelling amendment to the ANDA Norwich had submitted to FDA. Appx3968, Appx3978. According to Norwich, this amendment removed the HE indication—thus changing the indication of use—and prevented induced infringement of the HE Patents. Appx3978.

Although Norwich's motion cited Rule 60(b)(6), its arguments focused on Rule 60(b)(5). Norwich argued that its proposed modification was proper because its Amended ANDA "satisfie[d] the judgment" and rendered the judgment "no

longer equitable." Appx3980. Norwich asked the district court to summarily adjudicate that a claim "against Norwich's Amended ANDA would be futile." Appx3983; *see also* Appx3983-3986 ("Salix cannot state a plausible claim . . . against Norwich's Amended ANDA based on the Asserted HE Patents.").

In response, Salix explained that Norwich's unilateral decision to amend its ANDA was not "changed circumstances" that would warrant amending the judgment. Appx4148. Norwich should—like other litigants—have amended its ANDA before trial, not after. Appx4150. The only courts considering similar motions have denied them. *See* Appx4152-4153.

The District Court Denies the Motion to Amend

Agreeing with Salix, the district court denied Norwich's motion. Appx52. Norwich's amendment did not constitute "changed circumstances" justifying modification of the judgment: "The changed circumstance is simply a voluntary decision of the trial loser to change course, which is neither unanticipated nor unforeseeable." Appx54.

The district court also found the modification would have been inequitable: Norwich simply "d[id] not want to live with the consequences of [its strategic] choices." Appx54. "Defendant fully litigated the merits of its non-infringement and invalidity case, lost, and now seeks a way around the final judgment through Rule 60(b)." Appx55.

The district court additionally found Norwich failed to prove that it carved out the HE indication: "Defendant, other than saying it has successfully carved out the HE indication, and providing me the label, has presented no evidence in support of its assertion." Appx55.

The district court thus exercised its discretion and declined to grant Norwich the "unprecedented" relief that it sought. Appx56. "[I]t just seems wrong to me that a Defendant can litigate a case through trial and final judgment based on a particular ANDA, and then, after final judgment, change the ANDA to what it wishes it had." *Id.*

Norwich appealed the judgment and the denial of its Rule 60(b) motion in May 2023. Appx4243.

Norwich Sues FDA for Obeying the Judgment

While this appeal was pending, FDA granted "tentative approval" of Norwich's ANDA, recognizing that the judgment below prohibited final approval. Norwich then sued FDA in the District of Columbia in June 2023. *Norwich Pharms., Inc. v. Becerra*, No. 1:23-cv-01611 (D.D.C.). Salix intervened. Dkt. 12.

In that court, Norwich insists, inexplicably, that the judgment **allows** FDA to grant immediate approval to ANDA No. 214369. *See, e.g.*, Dkt. 49 at 3 ("[A]rguments that the Delaware Court Orders provide 'no choice' but to deny approval are based on FDA's misinterpretation of the Delaware Court Orders[.]").

There, Norwich contends that "the Delaware Court Orders do not pertain to Norwich's Amended ANDA," Dkt. 49 at 16, so FDA can (and must) finally approve it.

The district court held a hearing on cross-motions on October 6 and has not issued a ruling.

SUMMARY OF THE ARGUMENT IN RESPONSE

If this Court reaches the cross-appeal, it should affirm the judgment and the denial of Norwich's motion to modify the judgment under Rule 60(b). As the district court explained, permitting Norwich to evade the judgment by a post-judgment ANDA amendment would be unprecedented and prejudicial to Salix.

Norwich wrongly asserts that the **sole** purpose of the Hatch-Waxman Act is to bring generics to market as quickly as possible. From that faulty premise, it concludes that trial in a Hatch-Waxman suit adjudicates only whether an ANDA may be approved as it exists at a particular moment in time. Under Norwich's reasoning, a generic has the absolute right to evade a judgment by a post-judgment amendment, and the amended ANDA can (indeed, must) be approved without any scrutiny by the district court. In Norwich's view, the district court has no ability to consider whether a post-judgment amendment is unfair or prejudicial to the patent-holder.

Norwich is wrong. The Hatch-Waxman Act is not limited solely to furthering generic interests. It balances generic and brand interests within the pharmaceutical industry. Trial in a Hatch-Waxman suit adjudicates when an ANDA may be approved, and a judgment in favor of the plaintiff limits approval of that ANDA. If a generic wishes to amend, it has the right to do so **before trial** (and trial will thus consider whether the amended ANDA infringes). If a generic seeks to amend **after**

trial but before entry of judgment, the district court has the discretion whether to consider that amendment, based on "principles of fairness and prejudice to the patent-holder." *Ferring B.V. v. Watson Lab'ys, Inc.-Fla.*, 764 F.3d 1382, 1391 (Fed. Cir. 2014). But before a district court can allow approval of the amended ANDA, it must "reconsider [the] finding of infringement in light of [the] amended ANDA." *Id.* No case authorizes, much less requires, courts to alter their judgments to permit immediate approval of a subsequently amended ANDA with no opportunity by the patent-holder to challenge and present evidence related to whether the amended ANDA infringes. Instead, a generic wishing to "design around" a final judgment of infringement can file a new ANDA, with all of the procedural protections to the patent holder guaranteed by the Hatch-Waxman Act.

This statutory scheme—reflected in the district court's judgment below—balances generic and branded interests and should be followed by this Court. In contrast, Norwich's approach would permit generics to evade a final judgment and proceed directly to market without any opportunity for branded companies and courts to assess whether the amended ANDA induces infringement, frustrating a central feature of the Act. The portion of the judgment challenged in Norwich's cross-appeal should be affirmed.

ARGUMENT IN RESPONSE

III. The District Court Did Not Err in Entering Judgment.

A. The Hatch-Waxman Act Balances Generic and Brand Interests.

The Hatch-Waxman Act establishes a unique process to allow for the early adjudication of whether a new drug application may be approved. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). It "facilitates the early resolution of patent disputes between generic and pioneering drug companies." *Vanda Pharm., Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1126 (Fed. Cir. 2018) (quoting *Caraco Pharm. Lab'ys, Ltd. v. Forest Lab'ys, Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008)).

Norwich errs by suggesting that the Hatch-Waxman Act's only purpose is "bringing generics to market as quickly as possible." Norwich Br. 21 (citations omitted). To the contrary, as this Court has repeatedly held, the Hatch-Waxman Act "str[ikes] a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Vanda Pharm. Inc.*, 887 F.3d at 1126 (quoting *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)). It is "a complex statutory framework that tries to balance generic and brand interests within the pharmaceutical industry." *Celgene Corp. v. Mylan Pharm. Inc.*, 17 F.4th 1111, 1117 (Fed. Cir. 2021).

Norwich's premise—that any interpretation of the Act delaying generic entry must be rejected—conflicts with the policy balance struck by Congress.

B. A Section 271(e)(4) Order Sets the "Effective Date of Any Approval of the Drug . . . Involved in the Infringement."

Congress created "a highly artificial act of infringement" and mandated "specified consequences" for that act. *Eli Lilly*, 496 U.S. at 678. One consequence is that "the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A).

Consistent with the statute's plain text, this Court has explained that a Section 271(e)(4) order provides that "FDA may not approve the ANDA until the effective date specified by the district court." *In re Omeprazole Pat. Litig.*, 536 F.3d 1361, 1367 (Fed. Cir. 2008) ("If the FDA has not approved the ANDA before the district court determines that the patent has been infringed, the FDA may not approve the ANDA until the effective date specified by the district court under section 271(e)(4)(A)."); *see also Bayer AG v. Elan Pharm. Rsch. Corp.*, 212 F.3d 1241, 1245 (Fed. Cir. 2000) ("[T]he FDA cannot approve the ANDA until . . . the date the listed drug's patent expires, if the court finds the listed drug's patent infringed[.]" (citation omitted)).

The district court found that Norwich infringed under Section 271(e)(2) when it submitted "an application"—ANDA No. 214369—"for a drug . . . the use of which

is claimed in [the HE Patents]" because "the purpose of [the] submission [wa]s to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . the use of which is claimed in [the HE Patents] before the expiration of [the HE Patents]." 35 U.S.C. § 271(e)(2).

Because of this infringement, the district court was required to "order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of [the HE Patents]." 35 U.S.C. § 271(e)(4). When, as here, "the district court has entered a judgment finding that the operative ANDA infringes," it "must . . . enter a § 271(e)(4) . . . order." *Ferring*, 764 F.3d at 1391.

Consistent with the statute's plain text, the district court's order provides that "ANDA No. 214369" cannot be approved until expiration of the HE Patents.

After this judgment, if Norwich wanted approval of an ANDA that would not infringe the HE Claims, it needed to file a new ANDA, which would have afforded Salix all of the accompanying procedural protections under the Hatch-Waxman Act. At the very least, the district court had significant discretion whether to reconsider its judgment in light of Norwich's amendment to its ANDA.

1. Norwich's interpretation of the statute is untenable.

Norwich argues that a court must "tie the approval date to the . . . indication [that] is the source of the infringement." Norwich Br. 9. According to Norwich, the

requirement that the district court set the approval date for the "drug . . . involved in the infringement," 35 U.S.C. § 271(e)(4), acts as "a qualifier on the 271(e) order that ensures that the order is tailored to the actual act of infringement." Norwich Br. 18. Norwich thus contends that "the court had to specify that the approval date pertains to Norwich's ANDA" only so long as the ANDA "seek[s] approval for the infringing HE Indication." Norwich Br. 18.

This interpretation finds no support in the statute and makes no sense. Section 271(e)(4) mandates that a court set the approval date for a "drug" ("the drug . . . involved in the infringement"), not a particular label or particular indication:

> For an act of infringement described in paragraph (2)—
>
> > (A) the court shall order the effective date of any approval of **the drug** or veterinary biological product **involved in the infringement** to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

35 U.S.C. § 271(e)(4) (emphasis added). The phrase "involved in the infringement" clarifies which drug is being referenced.

Use of the definite article indicates that the scope of "the drug" is "specified in context." *Nielsen v. Preap*, 139 S.Ct. 954, 956 (2019) (quoting Merriam-Webster's Collegiate Dictionary 1294 (11th ed. 2005)). The adjectival phrase "involved in the infringement" provides that context, linking "the drug" to the "act of infringement described in paragraph (2)," the filing of the ANDA application.

Norwich also misinterprets statutory phrase "the infringement," arguing that "rifaximin is not 'involved in the infringement' when . . . it is sold or used for the IBS-D Indication." Norwich Br. 18. But "the infringement" refers to the (past) "act of infringement described in paragraph (2)," when Norwich filed an ANDA seeking approval for the HE indication. The "drug . . . involved in the infringement" was the drug for which Norwich sought approval in ANDA No. 214369.

After finding that Norwich committed an act of infringement when it submitted an application that would infringe the HE Patents, the district court was required to set the approval date for "the drug involved in the infringement" (the drug for which Norwich seeks approval in ANDA 214369) until after expiration of the HE Patents.

2. District courts correctly understand that Section 271(e)(4) orders set the approval date for the ANDA at issue.

District courts correctly understand the statute and regularly enter orders governing when FDA can finally approve ANDAs identified by number. For example, the judgment in *Exelixis, Inc. v. MSN Laboratories Private Ltd.* set "the effective date . . . of any final approval by the FDA of MSN's ANDA No. 213878."

Dkt. 331, No. 1:19-cv-02017 (D. Del. Jan. 30, 2023). This is the ordinary form of Section 271(e)(4) orders.[4]

To Salix's knowledge, no court has ever read the statute to require the form of judgment urged by Norwich, and at least one has considered and rejected such an

[4] *E.g.*, *Exela Pharma Scis., LLC v. Dr. Reddy's Lab'ys S.A.*, No. 1:20-cv-00365, Dkt. 255 (D. Del. Sept. 2, 2022) (setting "the effective date of any final approval of ['Abbreviated New Drug Application No. 214082']"). The following cases all contain similar language in the judgment. *Chiesi USA Inc. v. Aurobindo Pharma USA, Inc.*, No. 3:19-cv-18756, Dkt. 396 (D.N.J. Aug. 30, 2022); *Amgen v. Sandoz Inc.*, No. 3:18-cv-11026, Dkt. No. 525 (D.N.J. Oct. 12, 2021); *AstraZeneca AB v. Zydus Pharms. (USA) Inc.*, No. 1:18-cv-00664, Dkt. 187 (D. Del. July 28, 2022); *Hospira, Inc. v. Amneal Pharms. LLC*, No. 1:15-cv-00697, Dkt. 121 (D. Del. Feb. 6, 2018); *Merck Sharp & Dohme Corp. v. Actavis Lab'ys Fl, Inc.*, No. 3:15-cv-06075, Dkt. 225 (D.N.J. Dec. 12, 2017); *Novartis Pharms. v. Breckenridge Pharms. Inc.*, No. 1:14-cv-01043, Dkt. 193 (D. Del. May 16, 2017); *Endo Pharms. Sols. Inc. v. Custopharm Inc.*, No. 1:14-cv-0142, Dkt. 90, (D. Del. Feb. 28, 2017); *Bayer Pharma AG v. Watson Lab'ys Inc.*, No. 1:12-cv-01726, Dkt. 166 (D. Del. Dec. 28, 2016); *UCB, Inc. v. Accord Healthcare, Inc.*, No. 1:13-cv-01206, Dkt. 323 (D. Del. Sept. 2, 2016); *Reckitt Benckiser Pharms. Inc. v. Watson Lab'ys Inc.*, No. 1:13-cv-01674, Dkt. 452 (D. Del. Jun 28, 2016); *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, No. 3:11-cv-03962, Dkt. 361 (D.N.J. Nov. 16, 2015); *Merck & Cie v. Watson Lab'ys, Inc.*, No. 1:13-cv-00978, Dkt. 117 (D. Del. Sept. 14, 2015); *The Meds. Co. v. Mylan Inc.*, No. 1:11-cv-1285, Dkt. 615 (E.D. Ill. Nov. 12, 2014); *Avanir Pharms. Inc. v. Actavis S. Atl. LLC*, No. 1:11-cv-00704, Dkt. 496 (D. Del. May 15, 2014); *GlaxoSmithKline LLC v. Apotex Inc.*, No. 1:12-cv-01090, Dkt. 40 (D. Del. Apr. 9, 2014); *Allergan, Inc. v. Hi-Tech Pharmacal Co.*, No. 6:12-cv-0004, Dkt. 35 (E.D. Tex. Jan. 13, 2014); *Teva Pharms. USA, Inc. v. Mylan Pharms. Inc.*, No. 1:09-cv-08824, Dkt. 271 (S.D.N.Y. Dec. 20, 2013); *Teva Neuroscience, Inc. v. Watson Lab'ys, Inc.*, No. 2:10-cv-05078, Dkt. 553 (D.N.J. Dec. 13, 2013); *Bristol-Myers Squibb Co. v. Mylan Pharms. Inc.*, No. 1:09-cv-00651, Dkt. 243 (D. Del. Nov. 5, 2013); *Cadence Pharms. Inc. v. Exela Pharma Scis. LLC*, No. 1:11-cv-00733, Dkt. 476 (D. Del. Nov. 22, 2013); *Galderma Lab'ys Inc. v. Lupin Ltd.*, No. 1:10-cv-01112, Dkt. 35 (D. Del. July 18, 2012); *Mylan Pharms. Inc. v. Galderma Lab'ys Inc.*, No. 1:10-cv-00892, Dkt. 182 (D. Del. June 8, 2012).

argument. In *Onyx Therapeutics, Inc. v. Cipla Ltd.*, the defendant, like Norwich, sought a judgment that would allow it to "amend its ANDA to include new, noninfringing formulations." No. 1:16-cv-00988, Dkt. 548 at 2 (D. Del. May 8, 2020). The defendant proposed that the court order the effective date of final approval "of Cipla's ANDA No. 209479 . . . **to the extent as currently constituted respecting the formulation**." *Id.*, Dkt. 548-2 at 2 (emphasis added).

The plaintiff explained, as Salix did here, that the defendant "improperly attempt[ed] to 'carve out' of the judgment some unknown and unidentified future modification to the formulation of its proposed ANDA product." *Id.*, Dkt. 548 at 1. These speculative changes "ha[d] not been disclosed and were not part of the discovery." *Id.* "[I]f Cipla makes changes to its formulation that are not within the scope of the current ANDA product, that new product would require a new PIV certification and separate litigation." *Id.*

Then-Chief Judge Stark rejected the defendant's arguments and entered the judgment proposed by the plaintiff, setting the effective date of final approval of the ANDA, "including any amendments or supplements thereto" and without the defendant's proposed carveout language. *Id.*, Dkt. 549 at 2.

The defendant appealed, arguing that the judgment "is overbroad" and "should be limited to an injunction that precludes the use only of the infringing formulation." *Onyx Therapeutics, Inc. v. Cipla Ltd.*, No. 20-1875, Dkt. 19 at 59-60

(Fed. Cir.). The plaintiff defended the form of the judgment and argued (as Salix does here) that the defendant could have filed a new ANDA:

> If Cipla creates a formulation it believes would not infringe, Cipla can seek relief from the injunction or approval for that formulation by filing a new ANDA, each with attendant procedural safeguards. What Cipla cannot do is escape the statutory consequences of the district court's judgment—after Cipla litigated and lost in this action—based on some unknown hypothetical formulation.

Dkt. 32 at 65-66. This Court affirmed under Rule 36, 839 F. App'x 545, 546 (Fed. Cir. 2021), indicating that the panel believed that the judgment was "entered without an error of law." Fed. Cir. R. 36(a)(5).

Norwich cites only a single judgment that it claims is consistent with its interpretation of the Hatch-Waxman Act, but it was an agreed judgment. *Novartis Pharms. Corp. v. West-Warm Pharms.*, No. 1:15-cv-474, Dkt. 102 (D. Del.) (jointly proposed final judgment); *id.*, Dkt. 103 (final judgment); Appx3925-3926 (same final judgment). An agreed judgment is not persuasive authority that the statute requires a particular form of judgment.

Norwich incorrectly describes (at 22 n.2) the judgment in *Genzyme Corp. v. Zydus Pharmaceuticals (USA) Inc.*, No. 1:16-cv-00540 (D. Del. Aug. 21, 2018). Although that judgment mentions an indication as the basis for its finding of infringement, the decretal language correctly applies to the ANDA by number:

> [T]he effective date of approval of Defendant's ANDA No. 208980 shall not be prior to the expiration date of the '102 and '590 patents, except to the extent subsequently agreed between Plaintiffs and

> Defendant or ordered or otherwise permitted by this Court or other tribunal[.]

Dkt. 109 at 2. The judgment in *Genzyme* thus supports Salix, not Norwich.

C. Norwich's Argument Conflicts with This Court's Precedent.

This Court has already addressed how ANDA amendments affect trial and judgment: District courts have discretion whether to consider post-trial amendments to an ANDA, "guided by principles of fairness and prejudice to the patent-holder." *Ferring*, 764 F.3d at 1391.

In *Ferring*, the district court found that the ANDA at issue "permitted [the defendant] to sell an infringing product." *Id.* at 1386. During trial, the defendant "agreed to amend its ANDA specification to include a restriction" that would prevent infringement. *Id.* The defendant "amended its ANDA on February 10" (between trial and judgment), and FDA "approved the change on February 21." *Id.* "At a hearing on March 5, 2014, the district court concluded that the [amended] ANDA did not infringe the patents-in-suit." *Id.* at 1387. Based on this finding, the district court dismissed the case and did not enter a Section 271(e)(4) order. *Id.*

On appeal, this Court first explained that when a "challenged original ANDA [i]s amended during the pendency of litigation" (i.e., before trial), "this court and the district court conside[r] the amended ANDA in determining the issue of infringement." *Id.* at 1390 & n.7 (citing *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 124-75, 1278 (Fed. Cir. 2013)); *see also id.* (explaining that

"section 271(e)(2) and (4) require consideration" of an ANDA amended pretrial (citing *Bayer AG*, 212 F.3d at 1241)).

But where, as in *Ferring*, an ANDA amendment occurs between trial and judgment, a district court has discretion whether to "reconsider its own finding of infringement in light of an amended ANDA or other information." 764 F.3d at 1391. "We do not suggest that a district court must always consider any ANDA amendment. Allowing an amendment is within the discretion of the district court, guided by principles of fairness and prejudice to the patent-holder." *Id.*

This Court held that the *Ferring* district court "did not abuse its discretion in reconsidering its judgment of infringement in light of Apotex's amendment." *Id.* at 1392. Ferring failed to show "that it was prejudiced by the timing of Apotex's amendment." *Id.* Even though "the district court made clear that it was inclined to allow an amendment" and "discussed the language of the amendment on the record," Ferring "never requested that the district court reopen the record to address infringement by the [amended] ANDA." *Id.* at 1391-92.

Ferring thus confirms two key principles: (1) a district court has the discretion, not the obligation, to consider a post-trial ANDA amendment; and (2) if a district court considers a post-trial amendment in entering judgment, it must evaluate whether the amended ANDA would infringe (and provide the opportunity for the patent holder to present evidence and argument).

1. Unfairness and prejudice to Salix support the district court's exercise of discretion not to consider Norwich's hypothetical amendment.

The district court exercised its discretion not to consider Norwich's post-trial amendment to its ANDA. Norwich fails to show any abuse of discretion.

First, Norwich's amendment came far later than the amendment in *Ferring*. When the district court entered judgment, Norwich's amendment was purely hypothetical: it had neither submitted an amended ANDA to the district court nor proposed specific carveout language. Because the amendment was purely hypothetical, Salix had no opportunity to conduct discovery or submit evidence that it would infringe. *Cf. GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) (holding that a "skinny" label does not categorically foreclose infringement claims).

Norwich's hypothetical, future ANDA was not before the district court when it entered judgment: "Norwich's proposed ANDA has the HE indication. I cannot rule on facts that are not before me." Appx48. "That [potential future] label is not before me." *Id.* The only label before the district court was Norwich's original ANDA application, which infringed the HE Patents.

These facts contrast sharply with *Ferring*, where the amendment, including specific language, was discussed during trial. 764 F.3d at 1391. And in *Ferring*, FDA had approved the amendment before entry of judgment. *Id.* at 1386-87.

Second, on this record, allowing Norwich's untimely amendment would have caused significant unfairness and prejudice to Salix. The parties tried this case—and Salix made strategic decisions—based on Norwich's original ANDA. *See supra* pp. 3-4.

If Norwich had amended its ANDA before trial, Salix could have chosen to (1) seek discovery and present evidence that the amended ANDA infringes the HE Patents under *GSK*; (2) assert additional claims against the amended ANDA; or (3) spend additional time at trial presenting evidence and argument regarding the IBS-D Claims and Polymorph Claims.

Because Norwich proceeded to trial based on its original ANDA, considering Norwich's hypothetical post-trial amended ANDA would have caused unfairness and prejudice to Salix.

2. Norwich's position conflicts with *Ferring*.

Norwich's understanding of the Hatch-Waxman Act conflicts with *Ferring*. If a Section 271(e)(4) order only governs an ANDA as it exists at the time of trial (i.e., with the proposed label containing the particular language that formed the basis for the infringement finding), then a generic entrant could always nullify the judgment through amendment. A district court could never restrict FDA's ability to approve an amended ANDA.

This argument conflicts with *Ferring*, which holds that a district court may exercise its discretion and "reconsider its finding of infringement" in light of a post-trial ANDA amendment. 764 F.3d at 1391. If the amended ANDA does not infringe, the district court can decline to "enter an injunction or resetting order," *id.*, and thus allow final approval of the amended ANDA.

If Norwich were correct, a generic entrant would be better off not amending until after judgment. In Norwich's view, if the district court refuses to consider an amendment and instead enters a Section 271(e)(4) order based on a pre-amendment ANDA, the amended ANDA can receive approval from FDA without any judicial scrutiny. The generic would—by default—receive the same benefit as if the district court had considered the amended ANDA and found that it did not infringe. Trial court's judgments would be nothing more than readily evaded advisory opinions.

This case illustrates the absurdity of Norwich's position. The key premise of Norwich's brief is that its Amended ANDA no longer induces infringement of the HE Patents. *E.g.*, Norwich Br. 21 (asserting that it "remove[d] the infringing HE Indication"). But no court has ever considered whether Norwich's Amended ANDA infringes the HE Patents, and if Norwich were correct, then no court could ever consider that issue (at least not until after Salix has suffered irreparable injury from Norwich entering the market). This exemplifies the unfairness and prejudice to the patent-holder that *Ferring* empowers district courts to prevent.

The Hatch-Waxman Act allows branded pharmaceutical companies to accuse competing drugs of infringement before generic competitors launch (and before the patentee's market share is destroyed). Norwich's theory that it can launch a drug without any opportunity for judicial scrutiny of its ANDA conflicts with this basic premise of the Act.

In contrast, Salix's understanding of judgments comports with the Act, with *Ferring*, and with encouraging the practice of pretrial amendment. A Section 271(e)(4) order controls when the ANDA may be approved, regardless of any amendments. If the defendant wishes to amend its ANDA, it should do so pretrial. If the defendant amends post-trial, then the district court has discretion whether to reconsider its infringement finding under the amended ANDA. And if a defendant (such as Norwich) wishes to amend post-judgment, then it may file a new ANDA. At a minimum, a district court has at least as much discretion regarding post-judgment amendments as it does regarding post-trial amendments.

D. This Court's Interpretation of Section 271(e)(4) Orders Comports with FDA Regulations.

Norwich cites FDA regulations, Norwich Br. 20-21 (citing 21 C.F.R. § 314.94), but these regulations neither interpret Section 271(e)(4) nor instruct courts how to enter judgment. They are irrelevant to Norwich's cross-appeal. Norwich does not argue that these regulations are entitled to *Chevron* deference or identify any other principle under which these regulations would affect this Court's

statutory interpretation. Section 271(e)(4) concerns judgments entered by courts, a topic on which FDA has no expertise and would receive no deference, even if the regulations addressed court orders. *Cf. Smith v. Berryhill*, 139 S.Ct. 1765, 1779 (2019) (holding that Congress did not delegate to an agency the power to determine "the scope of the judicial power"); *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 650 (1990) (rejecting reliance on agency interpretations "to resolve ambiguities surrounding the scope of [a] judicially enforceable remedy").

FDA itself disclaimed any attempt to interpret Section 271(e)(4) in its regulations. As FDA explained in Norwich's D.C. district court litigation, its regulations simply reflect "default timing rules" that "may be overridden by court orders issued under the patent remedy statute." *Norwich Pharms., Inc. v. Becerra*, No. 1:23-cv-01611, Dkt. 52 at 15 (D.D.C. Aug. 16, 2023); *see also id.* (recognizing "that district courts have independent authority to shape relief under the patent remedy statute").

Norwich appears to be raising a surplusage argument by suggesting that FDA's regulations would be meaningless if this Court followed the statute's plain language. Norwich Br. 21. But Norwich cites no case holding that avoiding surplusage in **regulations** is a canon of **statutory** interpretation.

In any event, Norwich is wrong about surplusage. The regulations do not apply because they concern amendment only once "a court enters a final decision

from which no appeal has been or can be taken." 21 C.F.R. § 314.94(a)(12)(viii)(A). The judgment below is, of course, the subject of this appeal. *Cf. Banister v. Davis*, 140 S.Ct. 1698, 1708 (2020) (noting that the rules create "a single final judgment for appeal").

In addition, the regulations reinforce district courts' discretion to consider post-trial ANDA amendments. In *Ferring*, for example, the district court "found that Apotex's [original] ANDA No. 202286 infringed" but—exercising its discretion to consider the amended ANDA—declined to enter a Section 271(e)(4) order. 764 F.3d at 1387. Here, if the district court had reconsidered its finding of infringement in light of Norwich's post-trial amendment, it might have found that the HE Patents were infringed by the original ANDA but not the amended ANDA. In these circumstances, Section 314.94(a)(12)(viii)(A) would have provided FDA with a regulatory mechanism for finally approving the amended ANDA.

Salix does not, of course, contend that a district court can never consider a post-trial ANDA amendment. This Court has held that considering an "amendment is within the discretion of the district court, guided by principles of fairness and prejudice to the patent-holder," *Ferring*, 764 F.3d at 1391, and FDA's regulations operate comfortably within this framework. Even if Norwich's novel "regulatory surplusage" theory were a legitimate principle of statutory interpretation, it does not support Norwich's interpretation of Section 271(e)(4).

E. A Defendant Can "Design Around" a Section 271(e)(4) Order by Filing a New ANDA.

Finally, Norwich contends that it has the right to "design around" the infringement of the HE Patents. Norwich Br. 23-26. Salix agrees, but this fact does not support Norwich's position before this Court. Because Norwich proceeded to trial and judgment with an ANDA that induced infringement of the HE Patents, that ANDA (No. 214369) cannot be approved until the expiration of the HE Patents.

Norwich could "design around" the Section 271(e)(4) order by filing a new ANDA with a label that does not infringe. But if Norwich does so, Salix would receive all procedural protections of the Hatch-Waxman Act. *See also Onyx Therapeutics*, Dkt. 32 at 65-66 (Appellee: "If Cipla creates a formulation it believes would not infringe, Cipla can seek relief from the injunction or approval for that formulation by filing a new ANDA, each with attendant procedural safeguards."). As Congress intended, this process balances generic and brand interests.

A new ANDA would not be a mere formality. Not only does the label amendment undo the parties' stipulation, *see infra* pp. 62-63, but new patents have issued to Salix, including U.S. Patent No. 11,564,912 (Jan. 31, 2023), which claims methods of treating IBS-D that the Amended ANDA infringes.

Norwich cannot circumvent the protections Salix receives under the Hatch-Waxman Act by amending its ANDA post-judgment, after Salix had made strategic

decisions at trial based on the existing ANDA and when Salix would have no opportunity to argue that the Amended ANDA infringes.

* * *

Norwich does not appeal the finding that the operative ANDA induced infringement of the HE Patents at the time of judgment. The district court did not abuse its discretion in refusing to reconsider its finding of infringement in light of Norwich's hypothetical post-trial amendments. *See Ferring*, 764 F.3d at 1391 ("Allowing an amendment is within the discretion of the district court, guided by principles of fairness and prejudice to the patent-holder."). Based on its finding of infringement, the district court correctly followed the Hatch-Waxman Act to order that ANDA No. 214369 cannot be approved until expiration of the HE Patents.

IV. The District Court Did Not Abuse Its Discretion in Denying Norwich's Rule 60(b) Motion.

Rule 60(b) motions are "extraordinary relief which should be granted only where extraordinary justifying circumstances are present." *Bohus v. Beloff*, 950 F.2d 919, 930 (3d Cir. 1991) (citation omitted); *Gochin v. Thomas Jefferson Univ.*, 667 F. App'x 365, 367 (3d Cir. 2016) (same); *Gibson v. J.P. Harris Assocs.*, 637 F. App'x 58, 60 (3d Cir. 2016) (same). Norwich falls far short of showing "extraordinary justifying circumstances." Based on the facts before it, the district court acted well within its broad discretion in denying the motion.

A. Norwich Failed to Show an Abuse of Discretion Under Rule 60(b)(5).

Norwich's motion sought relief under Rule 60(b)(5), arguing that "the judgment has been satisfied" and that "applying it prospectively is no longer equitable." Fed. R. Civ. P. 60(b)(5). Neither argument is legally or factually correct.

1. Norwich has not "satisfied" the judgment.

With little explanation, Norwich contends that its "ANDA amendment satisfied the Final Judgment." Norwich Br. 27-28.

But the district court correctly recognized that in litigation between private parties, "the 'satisfied, released, or discharged' language is talking about money, and is therefore inapplicable." Appx53.

The first clause of Rule 60(b)(5) arises infrequently. *Frew v. Janek*, 780 F.3d 320, 327 (5th Cir. 2015). In a dispute between private parties, it generally arises "when there is a dispute over the amount of the [money] judgment." *Id.*; *see, e.g.*, *Sunderland v. City of Philadelphia*, 575 F.2d 1089, 1091 (3d Cir. 1978); *Nat'l Elevator Indus. v. McLaughlin*, 773 F. App'x 671, 672-73 (3d Cir. 2019).

In rare circumstances, the "satisfaction" clause of Rule 60(b)(5) has also been applied in "institutional reform litigation" against the government. *Horne v. Flores*, 557 U.S. 433, 447 (2009). Such litigation involves "sensitive federalism concerns" and injunctions that "often remain in force for many years," during which "the passage of time frequently brings about changed circumstances." *Id.* at 447-48.

Because of these features, courts "must take a 'flexible approach' to Rule 60(b)(5) motions addressing such decrees." *Id.* at 450.

Norwich cites three cases—none from the Third Circuit—to support its argument that it "satisfied" the judgment. Each involved express conditions in injunctions restraining governmental entities. *N. Carolina All. for Transp. Reform, Inc. v. U.S. Dep't of Transp.*, 713 F. Supp. 2d 491, 503 (M.D.N.C. 2010) ("issuance of environmental analysis and a new ROD"); *Sierra Club v. Mason*, 365 F. Supp. 47, 49 (D. Conn. 1973) (suit against Army Corps of Engineers requiring "filing of an impact statement");[5] *All. for Wild Rockies v. Kruger*, 15 F. Supp. 3d 1052, 1053 (D. Mont. 2014), *aff'd* 664 F. App'x 674 (9th Cir. 2016) (remanding to agency "to reexamine whether lynx 'may be present' under the appropriate standard, and, if so, to carry out consultation pursuant to ESA Section 7").

These cases have no bearing here. The judgment contains no condition for Norwich to "satisfy." This case is between private parties, and even in litigation against the government, "[t]he vast majority of motions for modification and termination of consent decrees, especially those involving institutional reform, invoke Rule 60(b)(5)'s third clause." *Frew*, 780 F.3d at 327.

[5] Moreover, *Sierra Club* relied on the third clause of Rule 60(b)(5): "[I]t is no longer equitable that the judgment should have prospective application." 365 F. Supp. at 49.

The Third Circuit appears to have applied the "satisfaction" clause of Rule 60(b)(5) only to money judgments. Norwich identifies no Third Circuit authority showing that the district court abused its discretion.

2. Norwich cannot show that changed circumstances require modifying the judgment.

This leaves Norwich with the third clause of Rule 60(b)(5), when it is "no longer equitable to apply the judgment prospectively." Fed. R. Civ. P. 60(b)(5).

For this clause, the Third Circuit has identified the "central" consideration as "whether the modification is sought because changed conditions **unforeseen by the parties** have made compliance substantially more onerous or have made the decree unworkable." *Bldg. & Constr. Trades Council of Phila. & Vicinity, AFL-CIO v. N.L.R.B.*, 64 F.3d 880, 888 (3d Cir. 1995) (emphasis added). Wright & Miller agrees that relief under Rule 60(b)(5) is unavailable when "changed circumstances were contemplated at the time the decree was entered." Mary Kaye Kane, *Federal Practice and Procedure* § 2863 (3d ed. 2022).

Here, there were no changed circumstances unforeseen by the parties—Norwich simply made a voluntary decision to seek amendment. The district court explained: "The changed circumstance is simply a voluntary decision of the trial loser to change course, which is neither unanticipated nor unforeseeable." Appx54.

Norwich had every opportunity to amend its ANDA before trial and secure a judgment on whether the amended ANDA infringes: "Defendant presents no facts

indicating that it could not have litigated the carve-out or that it was denied a full and fair opportunity to do so." Appx55. Norwich "fully litigated the merits of its non-infringement and invalidity case, lost, and now seeks a way around the final judgment through Rule 60(b)[.]" Appx55.

And to modify the judgment, the district court would have needed to find that the amended label does not infringe. "It is not a simple matter to determine whether an ANDA applicant has successfully carved out language from a label to turn infringement into non-infringement." Appx55. That determination would have required, in effect, "a second litigation." Appx55. For these reasons, the district court denied relief.

Norwich identifies no error in this analysis. Norwich faults the district court's citation to *Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367, 380 (1992), arguing "*Rufo* and cases like it all concern consent decrees or consent judgments." Norwich Br. 30.

But *Rufo* holds that consent decrees are subject to the ordinary standards of Rule 60(b)(5). *See* 502 U.S. at 380 (rejecting the argument that consent decree modifications were governed "by the [stricter] standard actually applied in *Swift*"). The Third Circuit similarly holds that "the standard for modifying an injunction cannot depend on whether the case is characterized as an institutional reform case, a commercial dispute, or private or public litigation." *Bldg. & Const. Trades Council*,

64 F.3d at 888. The district court neither quoted nor applied the "heavy burden" standard that Norwich criticizes as applicable only to consent decrees. *Compare* Norwich Br. 30, 32 *with* Appx53.

Norwich argues that courts should not "place emphasis on whether the change in circumstances was unexpected." Norwich Br. 30. It cites two district court cases for this proposition, neither from within the Third Circuit. Norwich makes no attempt to harmonize its arguments with the Third Circuit's holding that the "central" consideration is "whether the modification is sought because [of] changed conditions unforeseen by the parties." *Bldg. & Constr. Trades Council*, 64 F.3d at 888. This Court follows regional circuit law on this issue.

Norwich premises its criticism of the district court's analysis of the equities on its misinterpretation of the Hatch-Waxman Act. *See* Norwich Br. 31-32 (arguing that the statute "provides for amendment of an ANDA to carve out an infringing indication after a final judgment"). These arguments are addressed above. *See supra* pp. 37-54.

The district court's analysis of the equities was correct: Norwich cannot "litigate a case through trial and final judgment based on a particular ANDA, and then, after final judgment, change the ANDA to what it wishes it had started with, and win in a summary proceeding." Appx56.

Finally, Norwich argues that it "does not seek any determination . . . of any finding pertaining to the patent merits." Norwich Br. 32. Not so. In its motion, Norwich asked the district court to hold that "Salix could not state a claim for patent infringement of the Asserted HE Patents under . . . Norwich's Amended ANDA." Appx3983; *see also* Appx3985 ("Norwich's Amended ANDA proposes labeling that does not provide any reasonable basis to support a claim of induced infringement of the Asserted HE Patents."). The district court could only modify the judgment if it found that the Amended ANDA does not induce infringement of the HE Patents, but as the district court explained, it could not make that determination summarily. Appx55.

Norwich fails to show that the district court abused its discretion in denying relief under Rule 60(b)(5).

B. Norwich Failed to Show an Abuse of Discretion Under Rule 60(b)(6).

Norwich's motion focused almost exclusively on Rule 60(b)(5). Norwich cited Rule 60(b)(6)—and its "extraordinary circumstances" requirement—only in its recitation of the standard, not in its argument. Appx3980.

Even if Norwich preserved a Rule 60(b)(6) argument, it is meritless. The district court found that the current circumstances are not "extraordinary;" they are the result of Norwich making the conscious strategic choice not to amend its ANDA

pretrial (or even during trial). Appx55. The equities favor Salix, not Norwich, Appx54-55, and support the denial of relief under Rule 60(b)(6).

C. Granting Rule 60 Relief to Norwich Would Have Been Unprecedented.

As the district court recognized and Norwich does not deny, the relief Norwich sought was unprecedented. Norwich identifies no case modifying a judgment under Rule 60(b) based on the filing of an amended ANDA.

Courts have twice denied similar motions. In *Allergan, Inc. v. Sandoz Inc.*, 2013 WL 6253669 (E.D. Tex. Dec. 3, 2013), the defendant moved under Rule 60(b) for the court to "make a determination that Sandoz's amended ANDA does not infringe." *Id.* at *2. Like Norwich's Amended ANDA, "the amendment purport[ed] to carve out an infringing element in an attempt to escape the judgment." *Id.* at *3.

The district court rejected the argument that the defendant's foreseeable, intentional amendment justified modifying the judgment:

> The only changed circumstance that is relevant to Sandoz's non-infringement argument is the ANDA that it voluntarily amended after the Federal Circuit affirmed validity of the '149 patent. This was an intentional act that cannot be fairly characterized as unforeseen or unexpected.

Id. "[T]he changed ANDA occurred entirely through the actions of Sandoz and, by definition, is not beyond the defendant's control." *Id.* Sandoz—like Norwich—tried its case, lost, and sought "to change positions to obtain another chance at noninfringement via the modified ANDA." *Id.* Sandoz was required to "live with

the consequences of the choices it freely made, and the calculated decisions it strategically reached in the course of prior litigation." *Id.*

Norwich cannot distinguish *Allergan*, which involved a party seeking exactly the same post-judgment relief as Norwich.

Another court considered similar issues of ANDA amendment after trial and noted the need to "prevent a waste of judicial resources." *Forest Lab'ys, LLC v. Sigmapharm Lab'ys, LLC*, No. CV 14-1119-MSG, 2019 WL 3574249, at *7 (D. Del. Aug. 6, 2019). That court emphasized the importance of "certainty on the issues of infringement to be tested at trial" and recognized the significance that "there was no discussion at the trial . . . suggesting that [the defendant] would or should amend its ANDA to moot the issue of infringement." *Id.*

D. Norwich's Amendment Undoes the Parties' Stipulation.

Norwich's Amended ANDA creates an additional complication. Salix proceeded to trial only on nine claims, and for the remaining patents, the district court entered an agreed stipulated judgment of non-infringement. Appx3709-3713. But this stipulation applied only to "Norwich's current ANDA No. 214369," which included only "any amendments or supplements to the ANDA that do not change the indications of use." Appx3710 n.1.

Because Norwich's amendment changed the indications of use, the stipulation no longer applies. If the judgment were modified so that the Section 271(e)(4) order

did not apply to the Amended ANDA, the stipulated findings of non-infringement of the other claims should also be vacated and those claims should proceed to trial. Appx4156-4157. This fact further supported the district court's exercise of discretion.

* * *

Relief under Rule 60(b) is an extraordinary remedy. Norwich fails to show that the district court abused its discretion by denying the unprecedented relief it sought.

CONCLUSION AND PRAYER FOR RELIEF

Salix respectfully renews its request that this Court reverse the district court's judgment that the IBS-D Claims are invalid, render judgment that Norwich failed to show invalidity, and order FDA not to approve Norwich's ANDA until at least the expiration of the IBS-D Patents. Alternatively, this Court should vacate the invalidation and remand to the district court.

This Court should reverse the judgment that the Polymorph Claims are invalid, render judgment that Norwich failed to show invalidity, and order FDA not to approve Norwich's ANDA until at least the expiration of the Polymorph Patents.

If this Court grants Salix's requested relief on the IBS-D Claims, then Norwich's cross-appeal becomes moot. If this Court reaches the cross-appeal, then it should affirm.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(A)

1. This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 13,949 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Office 365 in Times New Roman 14-point font.

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